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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,814	12/21/2004	Isao Sakata	101512.55677US	8244

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,814	SAKATA ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/2004; 12/06/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the 371 of PCT/JP03/08016 filed December 21, 2004. Claims 1-18 are being examined on the merits herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is Shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-6, 9-12, and 15-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 2 of U.S. Patent No. 6,063,777 to Hikida et al. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the instant claims are claiming the same compound as the US Patent, namely an iminochlorine aspartic acid derivative of the compound of formula I. Thus the instant claims are not patentably distinct over US Patent 6,800,659 B2. Note that the "use of" language is seen as a product claim, thus these claims are also rejected under the disclosed product of '777.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims provide for the use of the iminochlorine aspartic acid derivative of the formula (I) or a pharmaceutically acceptable salt thereof is a sodium salt in PDT of rheumatoid arthritis (claims 5 and 6), inflammatory keratosis (claims 11 and 12), and to determine the location of a sentinel lymph node and the presence of cancer metastasis (claims 17 and 18), but, since the claims do not set forth any steps

involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

It is not clear how the location of the sentinel lymph nodes in claim 13 will be determined. More detail is necessary.

In the claims, the abbreviation of "PDT" is improper. It should be spelled out as photodynamic therapy.

Claims 3, 4, 9, 10, 15, and 16 are rejected as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3, 4, 9, 10, 15, and 16 are dependent on claim 1. A compound claim cannot depend on a method claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5, 6, 11, 12, 17, and 18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a

proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hikida et al. (US Patent No. 6,063,777).

Hikida teaches an iminochlorine aspartic acid derivative of the compound of formula I and pharmaceutically acceptable salts thereof (abstract, column 1, lines 8-10), in particular the sodium salt (column 6, lines 56-59), meeting the limitations of claims 3, 4, 9, 10, 15, and 16. Since the claimed compounds were administered, the compound inherently treats the claimed disorders/diseases. Note "use of " language as done in double patenting rejection.

Thus Hikida anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hikida et al. (US Patent No. 6,063,777) in view of Levy (Trends Biotechnology, 1995).

Hikida is discussed above. Hikida further teaches that the iminochlorine aspartic acid derivative of the compound of formula I, a photosensitizer molecule, is administered in photodynamic therapy (PDT) as a new method for the treatment of cancer. The porphyrin derivative is taken up by the cancerous tissues in the subject,

which is then followed by laser radiation causing selective destruction of the cancerous tissues (column 1, lines 15-26). Additionally, Hikida teaches that the use of this compound in PDT is extremely useful as a diagnostic agent for cancers and ophthalmic neurovascularization (column 13, lines 4-6, and the claims).

Hikida does not explicitly teach the use of the iminochlorine aspartic acid derivative of the compound of formula I for the treatments of rheumatoid arthritis, inflammatory keratosis, and explicitly cancer metastasis as determined by the location of a sentinel lymph node.

Levy teaches that the photosensitizer molecules that have been used both clinically and experimentally in PDT tend to accumulate selectively and be retained by abnormal or hyperproliferative cells, particularly those fed by neovasculature, such as cancer tissue (page 14, column 1, lines 16-20).

Levy further teaches as most photosensitizers currently being investigated in clinical studies exert their effect on tumors by their selective accumulation in both rapidly dividing or activated cells and neovasculature, any disease in which the underlying pathology involves these characteristics is a potential candidate for PDT (page 14, column 2, lines 10-19). Table 1 gives a partial list of such diseases and includes only those conditions for which there is some evidence, either clinical or preclinical, that PDT may have efficacy (page 16). These include psoriasis (i.e., inflammatory keratosis), macular degeneration of the retina, autoimmune conditions (i.e. rheumatoid arthritis), atherosclerosis and restenosis (page 16, lines 11-18). This

apparently disparate group of diseases has common underlying features in their pathology, which provide a common ground for treatment with PDT.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the iminochlorine aspartic acid derivative of the compound of formula I in PDT as a diagnostic agent for cancer as taught by Hikida to find the location of a sentinel lymph node in order to detect the presence of metastasis.

Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention to have applied the iminochlorine aspartic acid derivative of the compound of formula I as taught by Hikida for methods of treating the diseases as taught by Levy. The motivation is that it is logical to assume that other disease conditions, including metastasis, that have pathologies that involve rapidly dividing or activated cells and neovasculature would be amenable to treatment with PDT. Furthermore, because of its quick metabolism in a living body, it exhibits no toxicity against abnormal cells and would increase patient compliance as a result.

Further, since the claimed compound was administered, it is inherent that the claimed diseases/disorders were treated.

Conclusion

Claims 1-18 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY STUCKER can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER